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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,254

02/18/2004

Joel E. Bernstein

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23644 7590 10/09/2007  
BARNES & THORNBURG LLP  
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EXAMINER
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KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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10/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/781,254	<b>Applicant(s)</b> BERNSTEIN, JOEL E.	
	<b>Examiner</b> Jennifer Kim	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/18/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election without traverse of Group I (claims 1-7, 11 and 12) drawn to a composition comprising a preponderance of cis doxepin isomer over trans doxepin isomer, said cis doxepin isomer being present in an amount of about 0.01% to about 10.0% by weight, and a pharmaceutically acceptable vehicle, said composition for use in the treatment of affective, painful, allergic disorders, said composition being comparable in efficacy of compositions containing a preponderance of the trans doxepin isomer but with significantly less sedative effects is acknowledged.

Accordingly, claims 1-7, 11 and 12 are being examined and claims 8-10, 13 and 14 are withdrawn from consideration since they are non-elected invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The phrase "preponderance of cis doxepin isomer over trans doxepin isomer" renders claims 1 and 11 indefinite since it is not clear just how much more of cis doxepin isomer over trans doxepin isomer in order to meet the requirement of the term "preponderance". One of ordinary skill in the art would not be able to determine the amounts of cis doxepin isomer over trans doxepin isomer in order to practice Applicant's invention. The remaining claims are indefinite to the extent that they depend on claims 1 and 11.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission in view of Midha et al. (1992) of record.

Applicant admits that doxepin hydrochloride is most frequently used to treat the affective disorders depression and also employed less commonly for a treatment of a variety of painful and allergic disorder. (specification page 1, lines 4-7).

Applicant admits that doxepin is generally used topical application or ingestion formulation. (specification page 1, lines 8-10). Applicants admit that doxepin hydrochloride U.S.P. is a geometric isomer mixture "containing not less than 13.7% and not more than 18.1% of the cis isomer and "not less than 81.4% and not more than

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88.2% of the trans isomer. (specification page 1, lines 14-18). Applicants also admit that the systemic side effects (i.e. sedation) of doxepin occur in from 20% to over 60%, depending upon dosage and route of doxepin administration.

The difference between the primary reference and Applicant's claiming invention is amounts of cis doxepin isomer being "preponderance" over trans doxepin isomer and the degree of sedation effect of claims 1 and 11, the pharmaceutical formulations such as lotion, solution or cream etc., the amount of cis-isomer.

Midha et al. disclose that cis-doxepin component of the tricyclic anti-depressant doxepin is more active than trans-isomer. (abstract).

It would have been obvious to one of ordinary skill in the art to formulate doxepin comprising substantially more of the cis form of doxepin than trans-doxepin for the treatment of disorders (e.g. affective disorders) indicated to be effective with doxepin because cis-doxepin is more active than trans as disclosed by Midha et al. One would have been motivated to employ the composition comprising substantially more of cis isomer than trans isomer of doxepin to achieve at least comparable or superior benefit in the treatment of affective disorder therapy. The degree of desired sedation is obvious because as admitted by the Applicant that sedation of doxepin depends upon dosage and the route of doxepin administration as well known in the art by Applicant's admission. Moreover, the amounts of active agents to be used and the pharmaceutical forms, e.g., tablets, lotion etc; mode of administration are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional

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formulations of commercially available doxepin formulation and modes of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

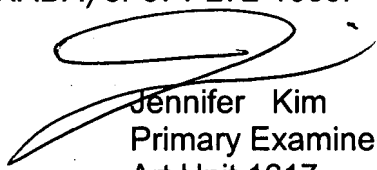
None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Jennifer Kim  
Primary Examiner  
Art Unit 1617

Jmk  
October 1, 2007